PARIS PROTOCOL TRADE REGULATIONS AND ACCESS TO MEDICINES:

A POLICY EVALUATION

Palestinian Health Capacity Project (PHCP)

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ACRONYMS

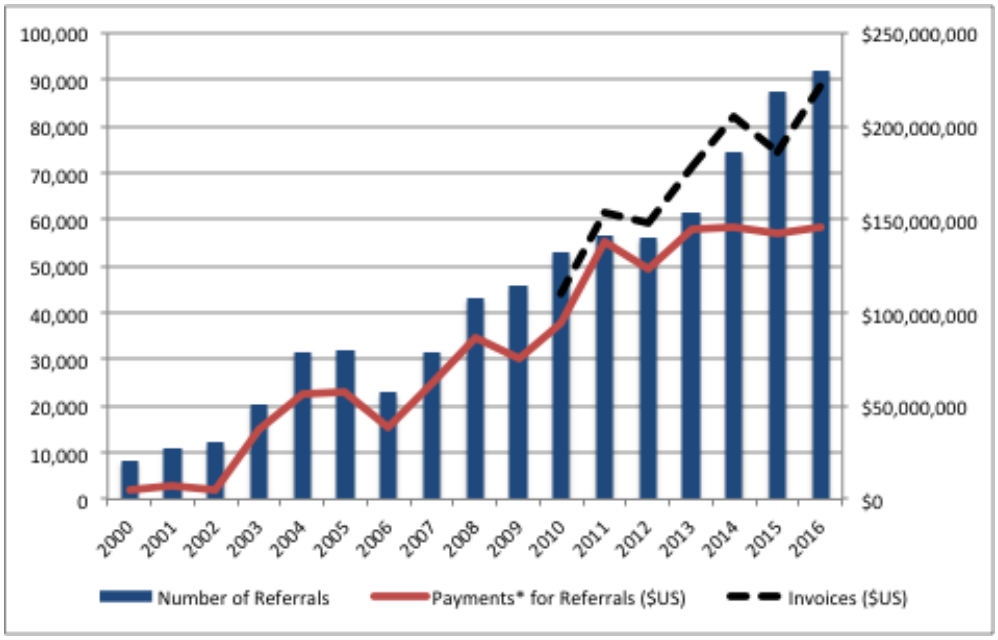
API	Active Pharmaceutical Ingredient
CMS	Central Medical Store
GCC	Gulf Cooperation Council
GDP	Good Distribution Practices (WHO Designation)
GMP	Good Manufacturing Practices (WHO Designation)
GS	Gaza Strip
HAI	Health Action International
IDA	IDA Foundation
IMF	International Monetary Fund
JPD	Joint Procurement Department (Jordan MOH)
MSH	Management Sciences for Health
NGO	Non-Governmental Organization
OOP	Out-of-Pocket (Individual Health Care Payments)
PA	Palestinian Authority
PHCP	Palestinian Health Capacity Project
PMOF	Palestinian Ministry of Finance
PMOH	Palestinian Ministry of Health
RFID	Radio Frequency Identification
SOW	Scope of Work
USAID	United States Agency for International Development
USD	United States Dollars
WB	World Bank
WB (geographic)	West Bank
WHO	World Health Organization

BACKGROUND

In 2017, PHCP and USAID commissioned Health Finance and Access Initiative (HFAAI) to conduct a health economic and financial assessment of non-PMOH hospitals and develop potential solutions that could improve both the short run financial gap faced by these hospitals and the sustainability of the overall Palestinian health system. Based on feedback via surveys, interviews, and the discussion of results with key stakeholders during the 'Financial Analysis of Palestinian Hospital Referrals' project, **access to medicines (particularly as a result of high prices or limitations in the supply chain) was consistently identified as a key issue affecting costs and quality of healthcare for both public and private sector health care providers in the Palestinian Territories. Moreover, many of the respondents indicated that the impact that the Paris Protocol trade regulations contributed to cost and access issues for medicines.**

Health care costs have grown rapidly for the PA, especially with respect to services and products consumed via referrals for private/NGO hospitals. (Figure 1).

Figure 1: PMOH Referrals and Costs over Time[1]



[1] Sources: PMOH Annual Health Reports [2016, p. 24; 2015, p.20; 2014, p.20], Economic Monitoring Report to the Ad Hoc Liaison Committee, World Bank, September 19, 2016; Rapid Assessment of Health Services Capacity in the West Bank: Palestinian Health Capacity Project (April 2014) Exchange Rate Assumptions ILS/$US (2016:3.889, 2015:3.902, 2014: 3.902, 2013: 3.611, 2012:3.856, 2011: 3.578, 2010: 3.739), PHCP and PMOH (Invoice data from 2010-2016).

*Note: Payments are typically delayed by 12-18 months in most cases. As such, we expect a lag between invoice and payment.

Medicines (even if charged at 'pass through' rates) can be a significant component of overall referral costs. In some cases, the medicine portion of invoices for contracted services approached 50% of overall referral costs for high acuity conditions such as cancer/oncology/nephrology at select providers. For example, Augusta Victoria costs for pharmaceuticals grew from 40% to 46% of the total invoiced amount for patient treatments between January-May of 2016 vs. 2017.[1] Yet, the impact of costly medicines and poor access extend beyond the costs incurred via referrals. The PMOH also purchases pharmaceuticals and there is a substantial private market that may be impacted by trade regulation and pricing policy.

There are multiple determinants that can impact access to medicines, but price and supply chain are two important components, particularly in lower- and middle-income country settings.[2-4] This report will examine the issues of access to medicines within the Palestinian health system, specifically focusing on how the Paris Protocols (which strongly influence many of the trade relationships between Israel and the PA) impact pricing and supply issues.

Pharmaceutical Expenditure, Market Size, and Market Characteristics

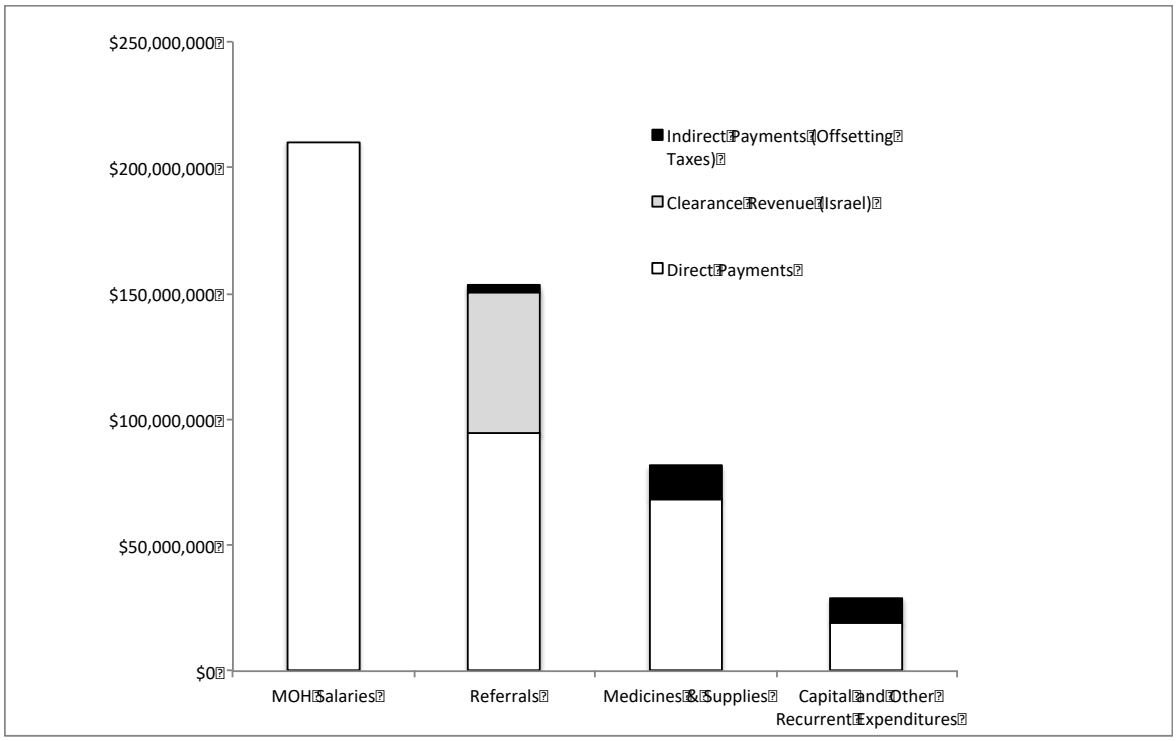
Market Size and Share (Public vs. Private Payer)

In 2016, pharmaceuticals and supplies accounted for 16% ($76M) of the PMOH budget, but this is just one portion of the total pharmaceutical expenditure within WB/GS/East Jerusalem.[5] Prior estimates of the private market (which may include OOP spending on pharmaceuticals and purchase by NGO/private facilities) peg it at roughly double the size of the public market. Based on 2008 data (most recently cited by WHO), the PMOH/WHO National Palestinian Pharmaceutical Profile indicated the private market was $100M USD (358M NIS, 2008) and the public market was $54M (194M NIS, 2008).[6] Another report estimated the pharmaceutical market to be on the order of $105M in 2005.[7,8] World Bank reports have also noted that a significant share of growth over time in health spending per capita in the West Bank and Gaza stems from private spending on pharmaceuticals.[8,9] **Assuming a rate of annual growth of between 4-5% per annum between 2008 and 2018, the size of the pharmaceutical market is likely $225-250M USD with approximately 65% of the market private and 35% public.** By comparison the Israeli market is estimated to grow to approximately $2B by 2020 (for a population of approximately 9M vs 5M in the Palestinian Territories). It is important to note that multiple factors contribute to expenditure differences across countries aside from price. The three main categories are price, volume (or utilization), and the mix of products used (e.g. generic vs branded technologies).

Table 1: 2016 PMOH Budget

GDP and Type of Expenditure	Estimate	Share of PMOH Expenditure	Source
GDP (Current $US)	$13.4 B	--	World Bank[1]
PMOH Expenditure	$477 M*	--	PMOH[2]
Referrals (Est. Cost)	$146 M	30.1 % (PMOH Exp)	PMOH[3]
Referrals (Act.)**	$163 M*	34.3 % (PMOH Exp)	PMOH[2]
PMOH Salaries (Act.)**	$218 M*	45.7 % (PMOH Exp)	PMOH[2]
Medicines/Supplies (Act.)**	$76 M*	15.9 % (PMOH Exp)	PMOH[2]
Capital Expense (Act.)**	$20 M*	4.2 % (PMOH Exp)	PMOH[2]

Figure 2: 2016 PMOH Expenditures (by Category) [2]



[2] Source: PMOH Annual Health Reports [2016, p. 274), Exchange Rate Assumptions ILS/$US (2016:3.889)

Market Shares (by Local/Foreign Producers)

Domestic and foreign firms both contribute substantially to the pharmaceutical market in the Palestinian Territories. With respect to 'product value' (or share of sales), prior estimates indicate that local producers and foreign firm split the market as each were responsible for 50% of sales.[6] We are assuming, for the purposes of this report, that these shares are still valid and are inclusive of both the public and private sectors of the market (although it is likely that the foreign importers may capture a somewhat larger share in the private market and the local manufacturers a larger share in the public market, in part due to industrial policy that slightly favors local provision for PMOH purchase of medicines with up to a 15% allowable markup in PMOH tenders for local manufacturers).[7]

In 2016 there were 1,968 drug products registered with the PMOH—57% of which were registered to foreign companies.[5] A prior analysis also suggests that many of the drugs on the Palestinian 'Essential Drugs List' (EDL) are sourced from importers (only 160 of 450 on the EDL were sourced from local producers)—but the number of products does not necessarily reflect sales volume shares or utilization/prescription counts.[7] Based on the share of private sector prices reported by the PMOH (West Bank only) in its 2016 Annual Health Report (p. 260), it appears that foreign firms (including Israeli manufacturers) are significantly more focused on selling to private payers.

Table 2: Local and Foreign Pharmaceutical Manufacturer Shares

Manufacturer Origin	Share of Registered Products (through 2016)	Pricing of Drugs for Private Sector in WB (through 2016)	Revenue Share (Total Market)	Volume Share (Total Market)
Local	42.8% (n=843)	16.3% (n=3,963)	50.0%	55.0%
Foreign	57.2% (n=1,125)	83.7% (n=20,315)	50.0%	45.0%
Source	Source: PMOH 2016 Health Annual Report (p.254)	Source: PMOH 2016 Health Annual Report (p.260)	Source: 2011 PMOH/WHO Pharmaceutical Country Profile	Source: 2011 PMOH/WHO Pharmaceutical Country Profile

The most recent WHO/PHCP pharmaceutical country survey indicated that there were six primary local manufacturers the majority of which have been approved as high-quality WHO-GMP facilities (Good Manufacturing Practices) by the WHO.[6] Prior analyses also suggest that those without GMP have received EU approval for their manufacturing processes, although this is of limited value given the regulatory difficulties involved in exporting outside the Palestinian Territories (in part stemming from Paris Protocol

related requirements). All local manufacturers appear to develop generic medicines, at least according to 2011 WHO/PMOH Pharmaceutical Profile which indicates that none of the facilities have R&D for discovery of new active substances or capacity to produce active pharmaceutical ingredients (APIs). This second point is particularly important for generic manufacturers since it indicates that API must first be imported as an input for their production process—APIs appear not to be produced locally.[6] As such, trade regulation can have an important impact on prices and supply of APIs, costs that can also get passed onto buyers. Table 3 summarizes how local and foreign manufacturing firms participate in the Palestinian market.

Table 3: Characteristics of Local and Foreign Firms in the Palestinian Pharmaceutical Market

Manufacturer Origin	General Production and Distribution Process	Product Types	Market Focus
Local (Palestinian)	Import API Manufacture and Sell Finished Products to Distributors/Facilities mainly in WB/GS (Limited Export)	Generic	Public Payers (PMOH)
Foreign (From Israel and ROW)	Manufacture and Export Finished Products to Distributors and Wholesalers in Israel or PA	On-Patent and Generic	Private Payers (NGO/OOP)

API=Active pharmaceutical ingredients, ROW=Rest of World

Table 4 summarizes the expected magnitude of the various market segments given plausible assumption about market growth and shares. Why do we care about this market data in the context of a policy analysis? These are important since adoption of trade reforms and policies may have different effects by segment and the relative impact will, in part, depend on the size of the relevant segment. For example, a regulation which permits improved access for APIs at lower prices in the WB/GS may reduce costs for the local, generic manufacturers, but it will not impact importers of on-patent branded medicines as significantly.

Table 4: Estimated 2018 Pharmaceutical Market Segment Size in Palestinian Territories ($US Mill.)

Total Market	$238 Mill.
Local Manufacturers	$119 Mill.
Foreign Manufacturers	$119 Mill.
Public Payer Market	$83 Mill.
Public | Local Manufacturers	$62 Mill.

Public | Foreign Manufacturers	$21 Mill.
Private Payer Market	$155 Mill.
Private | Local Manufacturers	$57 Mill.
Private | Foreign Manufacturers	$98 Mill.

Note: There is very limited data on the Palestinian market for medicines. These estimates are based on the total market size reported in 2008 ($154M) growing at 4% per annum through 2018. We assume that the public payer market share is 35% of the total market and the private market share 65%. Lastly, we assume that the foreign producers capture 25% of the Palestinian public market. This figure is consistent with previously reported estimates for the public market share fulfilled by foreign manufacturer firms.[7]

MEDICINE PRICES AND SUPPLY CHAIN

The Paris Protocols and Pricing of Pharmaceuticals

The central feature of the Paris Protocol regulations that most likely affects pricing of medicines is the "Central Customs and Taxation Envelope," which was summarized by Orly et al as follows (p.18):

> ""[For the vast majority of goods], it was decided that "Israel and the Palestinian Authority will employ for all imports the same system of importation, including inter alia standards, licensing, country of origin, valuation for customs purposes etc." [Article III 5(b)]. Moreover, this system of importation is based on the Israeli rates of customs and other import-related taxes (e.g. purchase tax), which would also serve as the minimum basis for the PA [Article III 5(a)]."" (p.18)

Effectively, this uniform customs agreement means that imports do not directly enter into Palestinian territories. Entry of products (both finished pharmaceuticals and APIs) can be restricted based on licensing and the manufacturer prices for goods are much more likely to be set on the basis of the Israeli market (due to the larger population size and significantly higher GDP/capita).

As such, the single price that manufacturers set (in particular with respect to on-patent medicines where manufactures have monopoly power to set price) are likely to exceed the price that would have been set by multinational medicine manufacturers had they been able to directly set prices specifically for the Palestinian market. Why would a monopolist set a low price for the Palestinian market? Figure 3 offers insight into the intuition of what is called 'price discrimination' or 'price differentiation,' which is a common tactic implemented in global pharmaceutical markets both within a across countries.[3,10-14] As the opportunity to set prices across segments increases, so too does

profit for the manufacture. It is also the case that a larger share of the population receives medicine (so access to medicines generally improves as well, particularly for lower income segments of the population).

Overall, it is to the manufacturer's advantage to set prices at lower levels for segments of the markets with lower demand (e.g. lower GDP per capita) and set prices at relatively high levels for segments of the market with higher demand (e.g. higher GDP per capita) *if markets can credibly be separated*. Firms with monopolistic power earn more profits if markets are 'separable' (meaning that there is no leakage of goods or prices between markets) and they can set differential prices across segments. This is particularly the case if costs of production for the manufacturer are low. Generally production costs for pharmaceuticals and medicines are low (the high costs are the research and development cost which are fixed and not relevant in this analysis).

Figure 3: Price Discrimination and Monopoly Profits

While prior policy papers suggest that pharmaceutical firms would prefer to set high prices and limit access to medicines in the WB/GS, there is, in fact, a rational argument in which these firms would benefit and be very supportive of a dual market, *if the Palestinian and Israeli markets could be credibly separated*. The effect of the Paris Protocol stipulations that result in single custom envelopes likely harms the manufacturing firms since it constrains the pricing decision to a 'single price' scenario across two different market segments.

Caveats for Price Discrimination

There are several nuances and important exceptions to this price discrimination 'rule' in which firms would prefer to be able to set multiple prices, especially lower ones in the Palestinian market relative to the Israeli market. **First, Israeli firms likely already have the capacity to set differential prices** between the Israeli market and the Palestinian market since they naturally are not 'exporting' to both countries simultaneously (as a non-Israeli multinational might). This may help explain why, in addition to proximal geography and a proportionally large industry footprint, Israeli firms possess such a large market share of the Palestinian market. Prior estimates suggest that approximately two-thirds of the non-Palestinian firm market is supplied by Israeli firms.[7] Naturally, Israeli firms would prefer to maintain their market share of the 'Palestinian export' market rather than allow entry of non-Israeli multinationals to compete on price under policies which allow differential pricing for a broader set of firms.

Second, **products with high marginal costs of production (such as advanced biotechnology therapies) are less amenable to price discrimination.** If the cost of production for a particular product is too high for the manufacturer, naturally there is only so low a profit-seeking firm will set price (firms will not set price below their perceived cost of production). Some of the products in oncology and other high-acuity conditions may fall into this category, but a large share of pharmaceutical products is relatively inexpensive to produce. If we see significantly lower prices in similar markets (Jordan, Egypt) for high priced products in Palestinian markets, it is likely the case that explanation for high prices in Palestinian market is not cost of production.

Third, **products with many substitutes (or a 'low elasticity of demand' in economic terms) are less likely to be priced significantly differently across markets.** If there are many substitutes, then prices are likely already relatively low due to competition from alternative substitutes. One would imagine that generic products may fall into this category, but 'elasticity of demand' is also very much a result of the clinical benefit. For example, we might imagine that demand for insulin is very significant while demand for cold therapies is less so. Moreover, generic markets are not always competitive. Sometimes there are limited suppliers even in a generic market and, as such, the degree of competition is limited, the capacity of similar products to enter is muted, and quasi-monopoly pricing (along with the preference for price discrimination across market segments) exists. The limited number of generic manufactures (and distributors/wholesalers) in the Palestinian market may result in lower competition across the supply chain (and higher mark ups/prices).

Fourth, **firms also set prices *within* fixed geographic markets, so prices in lower income markets (i.e. the Palestinian market relative to the Israeli market) may be higher than anticipated if there is a large disparity in income within the lower income market population or there are market segments with preferential access to resources** (e.g. external subsidies) in the low income market. For example, consider a multinational

firm setting price for a particular product specifically for the Palestinian market. If there is a range of income distribution (or even pockets of greater resources such as subsidized hospitals), the firm will be sensitive to these and may set prices at a relatively high level if price discrimination *within* the Palestinian market is not possible. Prior analyses have shown that it is not just overall resources of the country, but also the degree of equitable distribution of such resources, and the influence price in settings without the capacity to set prices differentially across sub-segments of the population. It is clearly not advisable to forego subsidization of any sort in WB/GS or E. Jerusalem medical institutions given the high level of clinical need and limited resources within WB/GS for both public and private markets. However, the development of policies or processes which effectively allow for price discrimination *within the Palestinian market* will help ensure that those with limited resources will maintain access to medicines. This is particularly important given a large share of medicines are purchased out-of-pocket (OOP) by Palestinian citizens (consistent with the pattern in many LMIC geographies). Addressing the Paris Protocols may allow for more significant price discrimination between Israel and Palestinian markets (e.g. lower prices in Palestinian markets), but access will be even more wide-spread if efforts are focused on how to prevent subsidized segments of the market (with relatively higher prices) from becoming distinct and separate from lower-resourced (lower income) segments of the market so firms can (rationally) offer even lower prices to low-income individuals than in subsidized institutions.

Fifth, **while manufacturers naturally set ex-manufacturing prices, mark-ups through the supply chain may result in higher-than-anticipated prices**. More will be discussed in the supply chain portion of this report, but essentially, if the degree of competition among distributors and warehouses for medicines is limited, than prices for retailers will be higher. Similarly, if there is limited competition across retailers (e.g. number of retailers/pharmacies with a particular product is limited) then markups by the retailers to consumers can also be substantial. Prior analyses of malaria markets and other LMIC analyses have demonstrated this behavior.[2,15-18]

Lastly, **government control/regulation of prices naturally also influences price levels**, but may do so differentially across market segments (public vs. private markets). For example, prices for medicines purchased by the public sector via a centralized tender process typically will be lower than disaggregated purchases. Governments may also use a range of pricing mechanisms to enforce price controls including internal and external reference pricing in which the price of the product (sometime for both public or private markets) is tied to the prices either of other products in the same market (e.g. generics that also treat the same condition) or to price level for the same product in different countries (e.g. external reference prices for the same product with 'peer' countries such as Egypt or Jordan). In some case, especially if there are limited resources to monitor prices in the private sector, the capacity of the government to influence price may be muted and focused primarily on public sector purchases. **One of the implications of the Paris Protocol is that it restricts the capacity of the PA to negotiate prices directly or develop effective pricing policies such as reference pricing with**

multinational manufacturers since pricing is effectively packaged for the Israeli market.

While there are several caveats to the voluntary price discrimination argument (in which we would anticipate lower prices in Palestinian territories if only markets could be separated), there are stakeholders (esp. ex-Israeli multinationals) that would welcome the capacity to have the market segmented and voluntarily set ex-manufacturer prices lower in the Palestinian market if possible. It is important to recognize this potential 'ally' when determining how stakeholders may approach revisions or adjustments to Paris Protocols.

Price Comparisons

How high are price levels for medicines in the Palestinian market relative to similar peer markets or international price standards? Only a few partial analyses have been conducted in this area since price data is limited, but they are instructive.

Table 5: Evaluations of Medicine Prices in the Palestinian Market

Evaluation/Type: Dwelk et al (as reported in World Bank 2009 Report)[8] / Quantitative **Methods/Data:** Compare MSH international tenders prices, PMOH procurement prices, private Palestinian market prices, UNRWA procurement prices, and Syrian prices (supplemental World Bank analysis) **Key Findings**: **PMOH prices were 6.9 times MSH tender prices, 4 times UNWRA prices, and 4.5 times Syrian prices. Palestinian private sector prices were generally larger than public sector prices**. **Implication**: Although dated, these differences likely persist (an update may be reasonable to commission given modifications in policy in the interim, e.g. greater efforts to rationalize medicine and regulate prices).
Evaluation/Type: Ewen et al, Journal of Pharmaceutical Policy and Practice, 2014[19] / Quantitative **Methods/Data**: UNWRA central tender prices and, in some cases, field prices from July 2011 (from distributors) for top 80 medicines (by value, 93% of all medicine expenditures) were compared to A) MSH international tender prices B) Jordan MOH Joint Procurement Department (JPD) prices C) Gulf Cooperation Council (GCC) prices and D) IDA Foundation (IDA) prices. **Key Findings**: While central tender median prices (sourced via Jordan) were competitive with international prices (median price ratios for centrally sourced UNWRA were .99, .98, 1.12 and 1.00 for MSH, GCC, IDA and JPD respectively) when sourced centrally from Jordan, **median prices for local sourced UNWRA products for the West Bank were 128% more than centrally sourced UNWRA costs (from Jordan).** **Implications**: Conditional on the generalizability of the small sample (n=18 medicine comparisons with West Bank sourcing), the costs are over twice as high in the West Bank vs. Jordan. Reasons for this could be high mark ups by distributors in the WB, more costly inputs (e.g. API costs) for WB manufacturers or a combination of the two factors. Addressing the API input costs via the Paris Protocol exemption for API may fix some of the issues, but supply chain competition should likely also be addressed in unison.

Table 5 (cont.): Evaluations of Medicine Prices in the Palestinian Market

Evaluation/Type: Hospital Finance Interviews and Pharmacy Survey/Qualitative **Methods/Data:** Interviews with Hospital Leadership at large NGO institutions/Survey to PMOH Pharmacy Director **Key Finding:** Respondents almost unanimously indicated that the **Paris Protocol led to substantially higher medicine prices than would otherwise be the case**. But it is not the only driver of high prices. One key factor that affects the price of medicines for public payers is **delayed payment, which results in higher costs** from suppliers to account for financing (this may now influence NGO hospital prices as well given the lag in payments from the PMOH to hospitals). Also, **distribution to E. Jerusalem is less costly** for some products, suggesting lack of competition in the supply chain may be more pronounced in WB/GS than E. Jerusalem for specific products. **PMOH staff does feel as though prices in the public market are better than the private market by 20% for generic medicines and 10% for branded/on-patent medicines** as a result of volume discounts related to annual public tender. **Mark-up levels by suppliers were estimated as 5-15% by the PMOH** pharmacy respondent (presumably for WB/GS locations rather the E. Jerusalem). Note this differs markedly from a World Bank 2009 estimate of 100% markup by distributors/agents and another 10-20% at the retail level.[8] **Implication**: Despite efforts to regulate price, the pricing imposed by the Paris Protocol is too pervasive to overcome for both government and private payers. However, additional effort in improving the supply chain competition will also lower prices, as will more prompt payment.
Evaluation/Type: PMOH/NGO report (as reported by World Bank)[9]/Quantitative (limited data) **Methods/Data:** A comparison of 2013 PMOH Central Medical Store (CMS) tender prices to WHO International Drug Price Indicator Guide (n=6 drugs) **Key Finding**: There is a wide variation of prices but prices were generally substantially larger in the WB. One ratio was 340% higher in the PMOH. **Implication**: The sample size was too small for any major conclusions, but it is confirmatory that public sector prices for the PMOH are well above international norms. Medicines appeared to include on-patent biologics.

While a full quantitative analysis was beyond the scope of work (SOW) for this project, we approached both USG and WHO personnel who referred to three potential data sets for price comparison: Management Sciences for Health (MSH) international price benchmark dataset (currently available up to 2015), Israeli Maximum Retail Prices (as posted on the Israeli MOH website) and the PMOH pharmacy website (which appears to

be ex-distributor price data). Future analyses of these sets are possible, but it is important to make adjustments for form, pill count/number of doses, year, and currency. **One of the key concerns would also be that these are prices taken at different points in the supply chain (pre- and post mark-up).** For example, the PMOH data appears to be the price that suppliers (distributors) charge payers and retailers (although the PMOH/WHO pharmaceutical profile indicates that there are price controls at the manufacturer, distributor, and retail level).[6] This is different than the price that retailers set for patients/customers (as in the Israeli data set that is posted). Moreover, in the case of the Israeli data, these are *maximum* prices, not actual audited prices. The MSH international tender prices also reflect an institutional payer perspective in which very large quantities are, in some cases, purchased.

The WHO periodically conducts pricing audits for select countries in particular years in both public and private supply chains at both the ex-manufacturer and retail level through its Health Action International (HAI) program, and often compares country prices to MSH international tender prices. However, no analysis has been conducted in the WB/GS to date.[6] One recommendation would be for the WHO to conduct such an analysis in the WB/GS so as to provide a stronger information platform to motivate policy change related to the Paris Protocol. Alternatively, the PMOH policy group could collaborate with neighboring government MOHs to develop more extensive price comparisons by class, market, and other sub-groups (although these likely would be most valid for the public market).

Despite the dearth of data, the analyses that have been conducted are informative and generally find that pricing within WB/GS is very elevated relative to international standards or peer countries.

Supply Chain

The supply chain can be broadly characterized as the set of organizations through which medicines are distributed as therapies ultimately make their way from the manufacturer to the patient. Table 6 splits these into four broad categories, but reality is more complex. Typically, multiple supply chains exist and these may span various geographic areas (district, regional, and national level organizations, just as in health system delivery).[18] For example, the same wholesaler may take the delivery of product for both public and private purchasers at different prices and deliver product to various types of institutions or even individual patients.

Very few countries have had their supply chains mapped formally, but evidence from experiments in the supply chain may help inform our thinking with respect to how the Paris Protocol trade regulation may interact with the Palestinian supply chain. First, experiments such as the Affordable Medicines Facility for Malaria (AMFm), which has subsequently been folded into operations in the Global Fund, have illustrated that it is not enough to simply reduce the costs of medicines at the top of the supply chain (the

AMFm subsidized manufacturers so that they would supply appropriate anti-malarials at equivalent cost to poor quality medicines). It is also important to ensure that there is sufficient competition at all levels of the supply chain. Even if there are regulations restricting prices at the retail level, LMICs with limited capacity to monitor and penalize excessive prices may find that the market realities do not match their statutory requirements. Generally, in the case of select Asian and African countries, the improvement in pricing was more likely to be retained throughout the supply chain if sufficient competition was present.[17] As such, one recommendation regarding any effort to adjust the Paris Protocol in hopes of reducing ex-manufacturer medicine prices should be complemented with efforts to engender competition and/or effectively regulate the warehouses, distributors, and suppliers so as to ensure that initial price reductions are not eliminated by increased mark-ups among intermediaries.

Table 6: Medicines Supply Chain in Palestinian Territories

Supply Chain Segment	Manufacturers	Warehouses/ Distributors	Retailers	Patients/ Payers
Segment Size	Six Local Producers[6]/39 Local Factories[20]	154 Drug Warehouses[20]	1,023 Pharmacies[5] (West Bank only) 81 Hospitals[5]	4.8 Million Population[20]
Financial Flows	Manufacturers set price depending on competition and regulatory constraints The Paris Protocol essentially eliminates the capacity for foreign firms to import at prices appropriate for the Palestinian market	Limited number of distributors results in significant mark-ups for public (15% according to PMOH survey, but much larger in earlier estimates) and private system (unknown mark-up in private system, but in theory there is price regulation from PMOH)	NGO hospitals indicate that their medicines are invoiced "at cost" or with minimal margin. Pharmacists, especially private, likely mark up depending on regional competitive dynamics and maybe even consumer characteristics.	Variation in co-insurance and copays (generally lower in public system). Limited private finance as majority of private pharmaceutical expenditure typically is OOP.
Product Flows	Local producers (generics only) generate over 55% of product volume Foreign firms (frequently Israeli producers) provide products for both generics and on-patent medicine markets	Distributors are not required to adhere to GDP (Good Distribution Practices), but PMOH does regulate. Licensing and regulatory requirements likely restrict competition. Foreign products are initially routed via Israeli distribution channels.	Delivery to PMOH hospitals and facilities typically occurs every two month from CMS. Potential for 'bullwhip' effect across supply chain given uncertainty of product demand. (PMOH CMS orders are annual.) ~20% stockout rate in PMOH facilities.	Pharmacy and hospital stockouts can impact access to medicines, but the larger issue is likely the high cost of medicines which may preclude many from taking appropriate medicines.

CONCLUSIONS AND RECOMMENDATIONS

There are two key policy goals that can improve pricing of medicines in the Palestinian market:

A. Delink the Israeli and Palestinian market (currently all APIs and finished medicine products imported to the Palestinian market must first be registered in Israel)
B. Encourage improved competition across the supply chain.

These goals should be pursued jointly as just the joint effects are greater than the sum of each part.

The following recommendations pertain to Objective A:

- Revise the Paris Protocol so as to allow registration of medicine products directly to the Palestinian Territories (with differential Arabic packaging so as to help avoid leakage back to Israel).
- Track goods through the supply chain with RFID and/or blockchain technology (where feasible) to help ensure product is monitored more carefully and can be verified by multiple parties—particularly those concerned about leakage. Presumably multinational importers may benefit from improved capacity for price discrimination across markets.
- The PMOH should partner with amenable multinational manufacturers to jointly advocate for policies that help separate the two markets.
- Finished products should be treated as a higher priority than API products (if only a subset of products can receive exemption from the Paris Protocol). The APIs only impact local (not foreign) manufacturers' cost structure for generics, but evidence (such as much lower pricing for the few generics that managed to get exported from the WB to other countries) suggests that higher pricing in the generics space (where local firms have preferential status as suppliers) is not the result of very high API costs as much as the market power of local manufacturers and supply chain actors in WB/GS.[8] If the calculations in Table 4 are sensible, a large share (perhaps 75%) of the local manufacturer sales is to the PMOH rather than private sector. Industrial policy (the preference to have a functioning and, ideally, vibrant pharmaceutical industry) in part justifies the premium conferred to local producers. Perhaps the subsidies could be somewhat smaller if API input costs were less, but if prices are established on the basis of 15%+ over the best price from foreign competitors (whose API costs do not change) during the PMOH tender process, than it is likely that prices will not be substantially affected by an exemption of API in the Paris Protocol (prior World Bank analyses also noted that PMOH tenders frequently had fewer than two competitors).[8]

One of the key points for this analysis is that, absent improvements in supply chain competition and dynamics, the price reduction potential caused by the relaxation of the Paris Protocol will be limited. As such, recommendations for Objective B are:

1. Eliminating unnecessary barriers to entry (e.g. registration fees or any excessively burdensome regulatory requirements) that preclude entry of distributors/agents, warehouses or pharmacies/dispensaries. Many of these have been previously argued for in earlier analyses.[8]
2. Maintaining or increasing investment in human resources (e.g. pharmacy students and/or logistics professionals) that source each of these organization types (more professionals in the long run increases the likelihood of more improved pharmacy and/or supplier competition)[3]

To the extent that the above policy objectives are met and prices for pharmaceuticals decline (or attenuate), note that reductions in pricing do not always translate into lower overall expenditure since more product is affordable and a larger share of the population may have the capacity to purchase given lower prices. The net effect on expenditures is likely to be less than the percent change in prices, but this means there is greater utilization of product and greater health benefit relative to a scenario in which prices are elevated (and utilization is lower).

Both effects mean utility and health improve for patients—our most important stakeholder.

[3] Currently there is an oversupply of pharmacy students in the Palestinian Territories.

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